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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,884	03/12/2004	Viswanathan Srinivasan	P24615	4898

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
03/01/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/798,884	**Applicant(s)** SRINIVASAN ET AL.
	Examiner ARADHANA SASAN	**Art Unit** 1615

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 February 2012 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Aradhana Sasan/ Examiner, Art Unit 1615	/Robert A. Wax/ Supervisory Patent Examiner, Art Unit 1615

Continuation of 11. does NOT place the application in condition for allowance because: Applicants' arguments filed 02/21/12 have been fully considered but are not persuasive. Regarding Fanara et al. (US 6,699,502 - "Fanara" hereafter) Applicants argue that this reference "… does not explain what exactly is to be understood by the phrase "very different pharmacokinetic profiles" and it is only with hindsight that one can interpret this passage to suggest to one of ordinary skill in the art to provide a dosage form which comprises two different active substances (having different half-lives), one released immediately … and the one released gradually and continuously after administration, and releases the two active substances in such a manner that the plasma concentration of one active substance is within a therapeutic range over a period which is coextensive with at least about 70% of the period over which the plasma concentration of the other active substance is within a therapeutic range." Applicants argue that the Examiner has failed to provide any (written or other) evidence which shows the differences in release rates of different active substances from a single dosage form result in and/or are conventionally used to provide plasma concentrations in a therapeutic range of two active substances (with different plasma half lives) present in the single dosage form over similar or substantially coextensive periods of time.

This is not persuasive since the same first active substance (morphine derivative having antitussive activity – codeine, hydrocodone bitartrate) and second active substance (decongestant – phenylephrine and pseudoephedrine) are disclosed in the pharmaceutical compositions by Fanara (Col. 2, lines 36-50). It is obvious that the therapeutic effect from the controlled release of the actives would be the result of the administration of the pharmaceutical composition. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants present two possible scenarios when two drugs "having very different pharmacokinetic profiles" are used in a single dosage form where there is no need for any overlap between the periods of a plasma concentration within the respective therapeutic ranges of the rapidly acting first drug and the second drug.

This is not persuasive because it would have been obvious to one with ordinary skill in the art that the period of therapeutic effectiveness of the first active substance would be coextensive with the period of therapeutic effectiveness of the second active substance, especially if the two active substances are related to similar (antitussive) therapeutic activities.

Applicants argue that the passage of Fanara (in Col. 2, lines 36-50) must be considered and assessed in the context of the entire disclosure of Fanara. Applicants argue that Fanara is completely silent with respect to the duration of action of the active substances, let alone the duration of action of one drug in relation to the duration of action of the other drug. Applicants argue that it is not clear why the alleged different possible interpretations of claim 117 make any difference in the instant context. Regarding the graphs on Page 7 of the Final Office Action (mailed 12/22/2011), Applicants state that the Examiner has not completely understood the meaning and implications of the rejected claims. Applicants argue that the overlap does not mean that there also is a 100% overlap in the periods over which the drugs show plasma concentrations within the therapeutic ranges thereof.

The interpretation is provided to show that the 70% coextensive therapeutic range of the at least second drug can be 70% within the therapeutic range of the first drug or that there is 70% overlap between the therapeutic ranges of the first drug and the at least second drug. Fanara clearly teaches that the "controlled-release pharmaceutical compositions can be used in combination with an immediate-release pharmaceutical composition for the same or for another active substance, in a single unit intended to be administered orally" (Col. 3, lines 32-37). This renders obvious the simultaneous or coextensive therapeutic range of more than one active drug in a single dosage form, as instantly claimed. It would be obvious to one of ordinary skill in the art that with the varying release profiles of the different actives, the "combined therapeutic effects" would only be accomplished if the plasma concentrations of the actives were within or "substantially coextensive" with the therapeutically effective range of the two actives.